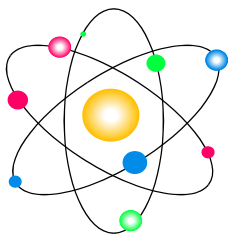
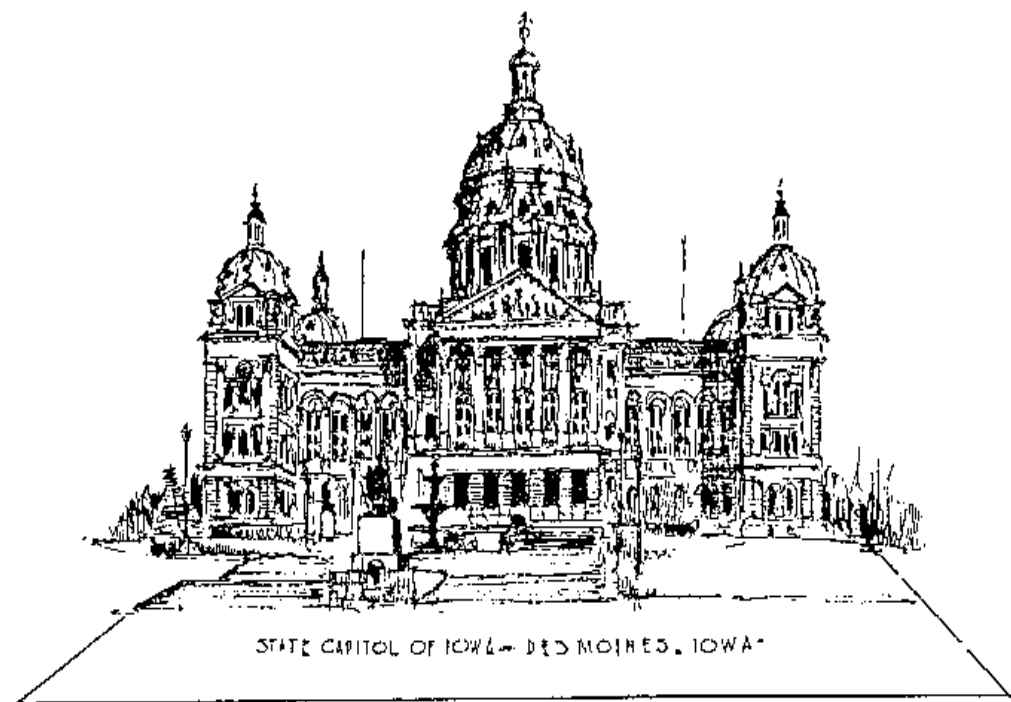

IOWA DEPARTMENT OF PUBLIC HEALTH

NUCLEAR PHARMACY REGULATORY GUIDE



Iowa Department of Public Health
Bureau of Radiological Health
Radioactive Materials Section
Lucas State Office Building, 5th Floor
321 East 12th Street
Des Moines, Iowa 50319-0075

IDPH REGULATORY GUIDE FOR NUCLEAR PHARMACY

1. INTRODUCTION.....	4
1.1 GENERAL	4
1.1.1 PURPOSE OF GUIDE	4
1.2 APPLICABLE REGULATIONS	4
1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA PHILOSOPHY)	4
2. FILING AN APPLICATION.....	5
3. CONTENT OF APPLICATION	5
ITEM 1.A. -- APPLICANT'S NAME AND MAILING ADDRESS.....	5
ITEM 1.B. -- LOCATIONS OF USE	6
ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION	6
ITEM 3. -- LICENSE INFORMATION	6
ITEM 4. -- INDIVIDUAL USERS	6
ITEM 5. -- RADIATION SAFETY OFFICER (RSO).....	6
ITEM 6. -- RADIOACTIVE MATERIAL AND ITEM 7. -- PURPOSE.....	7
ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM	7
ITEM 9. -- TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.....	7
ITEM 10. -- FACILITIES AND EQUIPMENT	7
10.1. -- ANNOTATED DRAWINGS.....	7
10.2. -- OTHER EQUIPMENT AND FACILITIES	8
10.3. -- ADDITIONAL RESPONSE FOR NUCLEAR PHARMACIES IN MULTITENANT BUILDINGS..	8
10.4. -- SPECIAL EQUIPMENT FOR HANDLING MILLICURIE QUANTITIES OF LIQUID RADIOIODINE.....	9
ITEM 11. -- RADIATION SAFETY PROGRAM.....	9
11.1. -- SEALED SOURCE INVENTORIES.....	10
11.2. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM.....	10
11.3. -- PROCEDURES FOR RETRIEVING RADIOACTIVE WASTE FROM CUSTOMERS.....	10
11.4. -- OPERATIONS	10
11.5. -- PRODUCT LABELS.....	11
11.6. -- PRODUCT SHIELDING	11
11.7. -- TRANSPORTATION.....	12
ITEM 12. -- WASTE MANAGEMENT	12
ITEM 13. -- LICENSE FEES.....	13
ITEM 14, 15 -- CERTIFICATION	13
4. AMENDMENTS TO LICENSE.....	13
5. RENEWAL OF LICENSE	13
6. IMPLEMENTATION	13
7. INSPECTIONS	14
APPENDICES	15
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA	15
DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO).....	19
MODEL DELEGATION OF AUTHORITY.....	21
MODEL TRAINING PROGRAM	22
MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS	23

MODEL PERSONNEL EXPOSURE MONITORING PROGRAM	26
<i>MODEL PROGRAM FOR EXTERNAL EXPOSURE</i>	26
<i>MODEL PROGRAM FOR INTERNAL EXPOSURE - BIOASSAYS</i>	27
MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES	29
MODEL RULES FOR SAFE USE OF RADIOPHARMACEUTICALS	31
MODEL SPILL PROCEDURES	33
MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	35
MODEL PROCEDURE FOR SAFELY OPENING PACKAGES	36
MEASURING AND RECORDING MOLYBDENUM CONCENTRATION (641-41.2(34))	38
MODEL PROCEDURE FOR AREA SURVEYS	39
MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS	41
REQUESTS FOR AUTHORIZATION TO REDISTRIBUTE VARIOUS ITEMS	45
MODEL PROCEDURE FOR WASTE DISPOSAL	48
SUPPLEMENT A	51
MODEL ANNUAL AUDIT CHECKLIST	51
SUMMARY OF REVISIONS	54

1. INTRODUCTION

1.1 GENERAL

The Iowa Department of Public Health (IDPH) regulates the possession, use, and distribution of by-product material in nuclear pharmacy operations. A specific license is required and the regulations governing nuclear pharmacies are contained in Chapters 39 and 41 of Iowa Radiation Machines and Radioactive Materials Rules. A license applicant should carefully study this guide and all the regulations in Chapters 39, 40 and 41 and before completing the application form, IDPH Form 299-0514. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program.

1.1.1 PURPOSE OF GUIDE

This guide is designed to describe the type and extent of information needed by the IDPH to evaluate an application for a new nuclear pharmacy license, an amendment to a license, or a license renewal. This regulatory guide's intent is to assist the applicant and licensee in understanding the regulatory requirements and the licensing policies as they apply to nuclear pharmacies.

A "nuclear pharmacy" prepares and distributes radioactive drugs to hospitals and to physicians. Nuclear pharmacies licensed by the Iowa Department of Public Health must make transfers of radiopharmaceuticals to specific licensees according to the requirements in 641-39.4(41). The term "distribution" may or may not involve a prescription for a specific patient.

1.2 APPLICABLE REGULATIONS

In addition to 641-41.2, other regulations pertaining to the medical use of by-product material are found in Chapters 38, 39, and 40 of the Radiation Machines and Radioactive Materials Rules. You may go to www.idph.state.ia.us and click on Health Protection and Environmental Health. Follow the links to the Bureau of Radiological Health. The regulatory guides can be found by further following the links to Radioactive Materials.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states "...Every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA)." As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

The Radiation Safety Officer (RSO) and management are required to audit the by-product material program to ensure the continued safe use of by-product material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing form 229-0514, "Application for Radioactive Materials License." You should complete Items 1 through 5, and 14/15 on the form itself. For Items 6 through 12, submit the required information on supplementary pages. Identify each sheet or document with the item number on the application. All typed papers, sketches, and drawings should be on 8 1/2 x 11-inch paper to facilitate handling and review, if possible. If larger drawings are necessary, fold them to 8 1/2 x 11 inches.

You should complete all items in the application in enough detail for the IDPH to determine that your equipment, facilities, training, experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the public in the IDPH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of propriety information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by IDPH.

Retain a copy of your application. The license incorporates the statements, representations, and supplements in your application as well as the requirements in the regulations. Statements and representations in the application or supporting documentation become enforceable as if they were regulations.

3. CONTENT OF APPLICATION

This portion of the guide explains, item by item, the information requested on IDPH Form 229-0514. The appendices to this guide serve to

- provide additional information on certain subject areas;
- provide a model procedure the applicant may adopt in response to an item on the application form; or
- provide an outline the applicant may use to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, or call 515-281-3478.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

The applicant should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 1.b.

ITEM 1.b. -- LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. If by-product material is used at more than one location, you must give the specific address of each location. In items 6 through 12 of the application, describe the intended use and the facilities and equipment at each location.

ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions only about the application. This individual, usually the Radiation Safety Officer (RSO) or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only. It would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to the CEO or President with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee if the CEO or President provides that authorization in writing to IDPH.

ITEM 3. -- LICENSE INFORMATION

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated for amendments or renewals.

ITEM 4. -- INDIVIDUAL USERS -- THEIR TRAINING AND EXPERIENCE

Authorized users must meet the requirements of 641-41.2(75) or 41.2(78). Provide the full name of each user and documentation of their training.

At least one individual named as an authorized user must be physically present when dispensing radiopharmaceuticals. Because nuclear pharmacy operations normally begin early in the morning and continue throughout the day, a sufficient number of authorized users must be available to ensure that all shifts have an authorized user in attendance.

ITEM 5. -- RADIATION SAFETY OFFICER (RSO)

You should name the person who will direct your day-to-day radiation safety program. The RSO you designate should be present daily at the facility. Without the RSO (e.g., in the early morning or when the RSO is sick or on vacation), authorized users must assume the RSO's duties. Appendix B outlines the typical duties and responsibilities of an RSO of a nuclear pharmacy.

Specify whether your RSO will have responsibilities in other areas such as serving as general manager, preparing and dispensing radiopharmaceuticals, calling on accounts, etc. If so, indicate the percentage of time that your RSO will be able to devote to the radiation safety program.

Any individual who has sufficient training and experience named as an authorized user is also considered qualified to serve as the day-to-day RSO. The training and experience of the proposed RSO should be submitted to the agency for review.

ITEM 6. -- RADIOACTIVE MATERIAL AND ITEM 7. -- PURPOSE

You should list the radioactive materials or wish to possess by

- (1) Radionuclide,
- (2) Chemical and physical form,
- (3) Maximum amount you wish to possess at any one time, and
- (4) Proposed use

If you want to redistribute various items containing radioactive material (e.g., generators, reagent kits, sealed sources. etc.), see Appendix P of this guide.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the program.

NOTE: Items 9. through 12.

Your response to these items should consist of one sentence that says that you will follow the model procedure in Appendix ___ in IDPH Pharmacy Regulatory Guide that you have enclosed your procedure for review; or the notation "NA" for "not applicable." Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your response to Items 9 through 12 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to name specific individuals, equipment by serial number, room numbers, or other site-specific information, there is no need to submit that procedure for review. Other than hot labs, procedures should allow for replacement of identical equipment and personnel.

ITEM 9. -- TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Describe your training program for individuals who work with or near radioactive material described in Item 6.a. See Appendix C of this guide.

ITEM 10. -- FACILITIES AND EQUIPMENT

10.1. -- ANNOTATED DRAWING

Submit an annotated drawing of the room or rooms and adjacent areas where by-product material usage takes place. Append it as ATT 10.1. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The direction of north.

3. Room numbers and principal use of each room or area (e.g., dispensing area, generator room, lounges, offices, file rooms, storage area, radioactive waste storage, rest rooms, closets, hallway).
4. Any shielding available.
5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors) including manufacturer and model or serial numbers where appropriate.

10.2. -- OTHER EQUIPMENT AND FACILITIES

Describe other equipment and facilities available for the use and/or storage of material described in Item 6 of this application.

For dose calibrator quality assurance testing, review Appendix D carefully. Commit to following the appendix or submit your own procedures using the appendix as a guide. Indicate "NA" if not appropriate.

Provide the manufacturer name, model number, and range of the survey instruments used for quantitative measurements. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 – 1,000 mR/hr
Lite Scientific, Inc.	DKM-007	1 – 100,000 cpm

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide on survey instrument calibration from the IDPH.

If you intend to provide services such as survey meter calibration or leak test analysis for other facilities, you must indicate in the application which service(s) will be provided. Submit the appropriate procedures for review.

Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery charges are not considered "servicing."

Describe the equipment and the methods used to measure the airflow rate. These airflow ratings may change with the seasons or as the equipment ages. Periodic measurements are necessary to ensure continued performance at the same ratings. At a minimum, airflow ratings should be measure at 6-month intervals. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application. Problems should be promptly corrected.

10.3 ADDITIONAL RESPONSE FOR NUCLEAR PHARMACIES IN MULTITENANT BUILDINGS

If radioactive material will be received, stored, or used frequently near a common wall, you should outline the access agreement with other tenants to allow you to perform the required surveys. Describe any alternate monitoring procedure (e.g., attaching film badges at specified intervals on the common wall).

You should state whether air from your suite could be circulated to other areas of the building by the heating/cooling system (e.g., via a common air space above ceiling tile, or by a central return duct). If so, you should show that rooms where volatile isotopes (e.g., Xenon-133, Iodine-131) are used or stored will

be maintained under negative pressure with respect to the rest of the building. Submit a facility diagram that indicates the location and the measured airflow ratings of the air supply and air exhaust vents.

10.4 SPECIAL EQUIPMENT FOR HANDLING MILLICURIE QUANTITIES OF LIQUID RADIOIODINE

If your operations will involve opening and dispensing millicurie quantities of liquid radioiodine, your facility must be equipped to maintain effluent releases of radioactive iodine at ALARA levels in accordance with paragraph 641-40.10(3) and 40.10(2). As a guideline, the IDPH staff uses 10% of the applicable limits. Most applicants use a charcoal filtration system in conjunction with their fume hood in order to achieve this goal. You should:

1. Specify that this work will be performed in a fume hood with adequate airflow. Airflow should be checked at 6-month intervals. Submit your procedures for review.
2. Show how you will maintain releases to the environment at ALARA levels. The general guideline is 10% of the limit specified in 641-40.27(2) and (3). Most applicants use a charcoal filtration system (or equivalent) system, you should describe the system and indicate the percentage of radioiodine that the system is expected to remove from the effluent. You should also estimate the concentrations of radioiodine in effluents released to the environment. Appendix O provides specific guidance on exposures to concentrations of gases. Other precautionary measures, including bioassays, should be described in the appropriate sections of the application.

ITEM 11. -- RADIATION SAFETY PROGRAM

The elements of a radiation safety program are contained in Appendices A through R. Review each appendix carefully. (Some of these appendices have been addressed in the proceeding text and need not be re-addressed.) Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate "not applicable."

Appendix A	Model program for maintaining occupational radiation exposure at medical institutions ALARA
Appendix B	Duties of the RSO
Appendix C	Training program
Appendix D	Model procedure for calibrating dose calibrators
Appendix E	Personnel exposure monitoring program
Appendix F	Reserved
Appendix G	Reserved
Appendix H	Leak-testing sealed sources
Appendix I	Safe use of radiopharmaceuticals
Appendix J	Spill procedures and action limits
Appendix K	Guidance for ordering and receiving radioactive material
Appendix L	Safely opening packages containing radioactive material
Appendix M	Measuring and recording molybdenum concentration
Appendix N	Area survey procedures
Appendix O.1	Estimating worker dose from concentrations of gases in work areas
Appendix O.2	Public dose from airborne effluent
Appendix O.3	Model procedure for calculating spilled gas clearance time
Appendix O.4	Records
Appendix P	Requests for authorization to redistribute various items
Appendix Q	Reserved
Appendix R	Model procedure for waste disposal

11.1. -- SEALED SOURCE INVENTORIES

State that you will conduct inventories, at intervals not to exceed 3 months to account for all sealed sources received and possessed under your license. You should maintain records of the inventories for at least 5 years from the date of the inventory. The records should include the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of inventory, and the signature of the Radiation Safety Officer.

11.2. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

40.10(3) requires an annual audit. Currently the IDPH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that once problems are identified they are promptly and comprehensibly corrected. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The IDPH will review a licensee's audit program and determine if corrective actions are through, timely, and sufficient to prevent recurrence.

The IDPH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with IDPH rules.

Supplement A contains a suggested audit program that is acceptable to the IDPH.

11.3 PROCEDURES FOR RETRIEVING RADIOACTIVE WASTE FROM CUSTOMERS

If you will retrieve radioactive waste from customers, you must:

1. Agree to retrieve only those items (e.g., syringes, and vials) that contain or are contaminated with radioactive materials that you supplied.
2. Agree to provide detailed instructions to customers that will package radioactive waste for return to your facility. These instructions must clearly indicate that you will accept only items that are contaminated or that contain radioactive materials. (The items must contain radioactive material that your facility has supplied to the customer.) In addition, the instructions must be adequate to provide for regulatory compliance for packaging and transport of licensed materials and for the radiation safety of drivers.
3. Submit a copy of the instructions that you provide to your customers concerning the return of radioactive waste.

If you wish to operate a waste disposal service on a broader scale, you may apply for a separate license under the general provisions of 641-39.4(25).

11.4 OPERATIONS

You must provide assurance that the products to be distributed either are manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act or are not subject to these Acts. You must also provide assurance that the Food and Drug Administration (FDA) has determined that the products you want to distribute are safe and effective.

In response to this item, submit a description of the operations you plan to conduct under your nuclear pharmacy license. The licensing criteria will be satisfied if the description of your operations specifies that:

1. Your nuclear pharmacy is licensed by the State Board of Pharmacy in the State in which the facility is located; you should submit a copy of the permit or license;
2. The activities of your nuclear pharmacy are limited to the preparation of radiopharmaceuticals for delivery by prescription to physicians within a specified geographical area;
3. Nuclear pharmacies must maintain a copy of each customer's current radioactive materials license to ensure that facilities receive only authorized radiopharmaceuticals.
4. The activity of your nuclear pharmacy is limited to:
 - a. repackaging IND/NDA¹ radiopharmaceuticals or
 - b. preparing radiopharmaceuticals by tagging IND/NDA reagent kits with a radionuclide eluted from an IND/NDA generator by following the procedures on the labels of the reagent kit, the generator, or both.

11.5 PRODUCT LABELS

Product labels must fulfill the color, symbol, and wording requirements of 641-40.60 through 40.63, and 641-39.4(29)“(4)”. They must contain sufficient information to prevent errors that lead to misadministration. Labels for containers of radiopharmaceuticals tagged with Technetium-99m should specify the total activity or concentration of Molybdenum-99. An expiration date and time should also be provided to ensure that no single patient dose at the time of administration will contain more than 1 microcurie of Molybdenum-99 per millicurie of Technetium-99m. The regulatory limits are specified in paragraph 641-41.2(34)“(a)”.

If the vial or unit-dose syringe can accidentally become separated from the shield in which it is distributed, both the vial or syringe and the shield must bear all the required labeling. Because of the limited surface area on the unit-dose syringe, the syringe label may bear the radiation caution symbol, the words "CAUTION, RADIOACTIVE MATERIAL." A prescription number that links the label to complete information on the unit-dose container shield or the prescription form also must be included. All other labels must be complete.

11.6 PRODUCT SHIELDING

The shielding you provide for each product you wish to distribute must be adequate for safe handling and storage of the product at physicians' offices and community hospitals.

¹ IND refers to pharmaceuticals, generators, or reagent kits for which the FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug." NDA refers to pharmaceuticals, generators, or reagent kits for which the FDA has approved a New Drug Application. For IND products, a nuclear pharmacy must:

- Dispense or distribute IND products in accordance with directions provided by the sponsor of the IND;
- Dispense or distribute IND products only to physicians who have been accepted by the sponsor of the IND to participate in the clinical evaluation of the IND product; and
- Inform each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the IND product in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the IND product.

For each radionuclide you intend to distribute, you should:

1. State the maximum activity for each type of container (e.g., vial, and syringe).
2. Describe the type and thickness of the shielding you will provide for each type of container.
3. Indicate the maximum radiation level to be expected at the surface of each type of shielded container when filled with the maximum activity. **The dose rate limits that DOT imposes apply to the surface of the shipping container rather than the surface of the shielded syringe or vial. 641-39.4(29)''(3) applies specifically to safe handling and storage of the final source container by group medical licensees.**

11.7. TRANSPORTATION

All licensees are required to comply with 641-39.5 regarding transportation of licensed material. The mobile nuclear medicine service acts as a shipper and carrier of radioactive material. Review of mobile van licensee inspection reports indicates a relatively high incidence of violations pertaining to transportation, even when the license was conditioned to alert the licensee of the requirements in 641-39.5. Therefore, the applicant should provide a description of the mechanisms or procedures used to assure the following:

- A. Transportation of radioactive material is in accordance with 641-39.5. Procedures should include:
 1. Approved packages
 2. Appropriate labeling
 3. Proper surveys
 4. Complete and accurate shipping papers
 5. Bracing of packages
 6. Security provisions
 7. Emergency procedures
- B. Training for drivers and technologists in transportation regulations and emergency procedures. Documentation of this training should minimally include dates, topics discussed, attendees and instructor's name.
- C. Quarterly management audits of transportation documentation and temporary job site activities (i.e., shipping papers, survey reports, etc.)
- D. Emergency procedures that van drivers shall follow in case of an accident involving licensed material in transport shall be maintained in the vehicle during transport. Emergency procedures should minimally include posting the area, maintaining surveillance, and notifying the RSO. A copy of these procedures must be included in the application.
- E. Procedures for handling radioactive waste during transport. Describe the method of storage and final disposal.

ITEM 12. -- WASTE MANAGEMENT

Submit your procedures for waste disposal. See Appendix R. Be sure to include a procedure for all material listed in Item 6.

ITEM 13. -- LICENSE FEES

1. An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at www.idph.state.ia.us. An application received without a fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.
2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.
3. Review 39.4(26) "Financial Assurance and Recordkeeping for Decommissioning." Submit financial assurance as described or provide information that exempts the facility.

ITEM 14, 15 -- CERTIFICATION

The application must be signed by a senior partner, the president, director or chief executive officer. Identify the title of the office held by the individual who signs the application.

If the senior partner, president, director, or chief executive officer wishes another person to sign the application, a delegation of authority must be enclosed. The delegation of authority signed by the senior partner, president, director, or chief executive officer should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later.

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. An application for an amendment must be filed on IDPH Form 299-0514 or as a letter and must be signed by the person delegated in Item 14/15. The appropriate fee must be included.

The licensee may not place into effect any amendment until receiving written verification from the IDPH that the amendment has been approved.

5. RENEWAL OF LICENSE

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by the IDPH as provided for in paragraph 641-39.4(34). The application for the renewal should not reference material that was previously submitted.

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating IDPH regulations that do not allow you to possess licensable material without a valid license.

6. IMPLEMENTATION

The information in this regulatory guide is guidance, not requirement. The IDPH reviews each application to ensure that users of by-product material are capable of complying with IDPH's regulations. This guide

provides one set of methods approved by the IDPH for meeting the regulations and represents the minimum acceptable standards.

7. INSPECTIONS

IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule.

APPENDIX A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

In addition to 641-41.2(7)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix A to IDPH Pharmacy Regulatory Guide" and submit a signed copy of section 5 of this appendix.

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program and a signed copy of section 5 of this appendix.

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

- a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far as below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. RADIATION SAFETY OFFICER COMMITMENT

- a. Annual and Quarterly Review
 - (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
 - (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of section 4 of this appendix.

b. Education Responsibilities for ALARA Program

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
- (3) Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

d. Reviewing Instances of Deviation from Good ALARA Practices:

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3. AUTHORIZED USERS COMMITMENT

a. New methods of Use Involving Potential Radiation Doses

- (1) The authorized user will consult the RSO during the planning stage before using radioactive materials for new uses.
- (2) The authorized user will review each planned use of radioactive materials to ensure that uses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

- (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
- (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES¹

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

¹ IDPH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

TABLE 1		
INVESTIGATIONAL LEVELS		
Investigational Levels (mrems per month)		
	Level I	Level II
1. Total Dose Equivalent: whole body; head and trunk; active blood- forming organs; or gonads	200	400
2. Skin of whole body, extremities	2000	4000
3. Lens of eyes	600	1200

The RSO will review and record on IDPH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 641-40.100. The following actions will be taken at the investigational levels as stated in Table 1:

- a. Personnel dose less than Investigational Level I:

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the investigational Level I.

- b. Personnel doses equal to or greater than Investigation Level I but less than Investigational Level II:

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews to management as soon as completed. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required. The RSO and management will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

- c. Personnel dose equal to or greater than Investigational Level II:

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's Form IDPH 588-2834 "Occupational Exposure Record for Monitoring Period" and 588-2833 "Cumulative Occupational Exposure History" or its equivalent.

- d. Re-establishment of investigational levels to levels above those listed in Table I.

In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

5. SIGNATURE OF CERTIFYING OFFICIAL¹ Sign and submit as part of Appendix A.

I hereby certify that this institution has implemented the ALARA Program as set forth above.

Signature

Name (Print or type)

Title

¹ The person who is authorized to make commitments for the administration of the institution (e.g., CEO, president, etc.).

APPENDIX B

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

In Addition to 41.2(8)

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for RSO that was published in Appendix B to the IDPH Pharmacy Regulatory Guide."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Iowa Rules. Say on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

MODEL PROCEDURE

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or IDPH inspections.
3. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
 - a. The licensee is abiding by IDPH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
 - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
 - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with IDPH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least 3 years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation more than ALARA levels or Chapter 40 limits are investigated and reported to IDPH within the required time limits.
10. Ensure that fume hood flow rates are tested at appropriate intervals and that employees utilize hoods in accordance with the safe use of radiopharmaceuticals.
11. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
12. Ensure that licensed material is disposed of properly.
13. Ensure that the facility has up-to-date copies of IDPH's regulations, completing a review of new or amended IDPH regulations, and revising licensee procedures, as needed, to comply with IDPH regulations.

14. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to IDPH in the licensing process.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with rules. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to request amendment changes and raise issues with the Iowa Department of Public Health, Bureau of Radiological Health at any time.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected Department Heads

APPENDIX C

MODEL TRAINING PROGRAM

In addition to 641-40.111 and 641-41.2(8)"b"(2)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix C to IDPH Nuclear Pharmacy Regulatory Guide." You may use lectures, videos-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.111. Say on your application, "We have developed a training program for your review that is appended as Appendix C." Be sure to include the groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instructions have been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel to be instructed:

1. All workers that might receive an occupational dose.
2. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material.

Frequency of instruction:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects in addition to 40.111:

1. Applicable regulations and license conditions.
2. Licensee's in-house work rules.
3. Locations where the licensees have posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 641-40.110.
4. Question and answer period.
5. Record of date of program, subject and attendees.

APPENDIX D

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

In addition to 641-41.2(17)

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix D to IDPH Nuclear Pharmacy Regulatory Guide."

If you develop your own dose calibrator calibration procedure for review, you should carefully review 641-41.2(17) and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as Appendix D," and submit your dose calibrator calibration procedure.

MODEL PROCEDURE

1. Test at the indicated frequency in 41.2(17). Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of ± 5 are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.
2. Constancy means reproducibility in measuring a constant source over a long period. In addition to the requirements of 41.2(17)"b"(1), consider the use of two or more sources with different photon energies and activities. Use the following procedure:
 - a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
 - b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.
 - c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
 - d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
 - e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds ± 10 percent.
4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.
5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator according to the requirements of 41.2(17)"b"(3). This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed. The vial or syringe may be in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

DECAY METHOD

- a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8 a.m.
- b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than the amount specified in 41.2(17)"b"(30). For dose calibrators with a range selection switch, select the range you would normally use for the measurement.
- c. Convert the recorded time and date to hours elapsed.
- d. On a sheet of semilog graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.
- e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. $(A - \text{observed} - A\text{-line}) / (A\text{-line}) = \text{deviation}$.
- f. Put a sticker on the dose calibrator that says when the next linearity test is due.

SHIELD METHOD

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the "sleeves" must be performed each time the dose calibrator is returned from repair.

Follow the manufacturer's instructions when performing the linearity test.

6. Geometry independence means that the indicated activity does not change with volume or configuration and is conducted in accordance with 41.2(17)"b"(4). This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.
 - a. In a small beaker or vial, mix 2.0 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
 - b. Draw 0.5 cc of the Tc-99m solution into the syringes and assay. Record the volume and millicuries.
 - c. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
 - d. Repeat the process until you have assayed a 2.0 - cc volume.
 - e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "Standard volume."
 - f. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." This will also be necessary if any data points lie outside the 5 percent error lines. Be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

- g. To test the geometry dependence of a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
 - h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries indicated.
 - i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
 - j. Select as a standard the volume closest to that normally used for mixing radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."
 - k. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." This will also be necessary if any data points lie outside the 5 percent error lines. Be sure to label the table or graph "vial" geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
7. Accuracy means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier. The supplier must compare that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. In addition to the requirements of 41.2(17)"b"(2), consider using at least one reference source whose activity is within the range of activities normally assayed.
- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for three determinations.
 - b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.
 - c. Repeat the procedure for other calibrated reference sources.
 - d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.
 - e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values.
 - f. Place a sticker on the dose calibrator that indicates when the next accuracy test is due.
8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

APPENDIX E

MODEL PERSONNEL EXPOSURE MONITORING PROGRAM

In addition to 641-40.36 and 40.37

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application. "We will establish and implement the model personnel exposure monitoring program published in Appendix E.1 and/or E.2 to IDPH Nuclear Pharmacy Regulatory Guide."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.36 and 40.37. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix E" and submit your monitoring program.

E.1. MODEL PROGRAM FOR EXTERNAL EXPOSURE

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor. The device will be processed by a contract service on a monthly basis if they exceed 500 millirem per quarter. Those licensees whose employees receive exposures of less than 500 millirem a quarter may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:
 - Supporting documentation that confirms that no employee will exceed 500 millirem/ quarter; and
 - proposed frequency of exchange.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or finger monitor. The device should be processed by a contract service on a monthly. Those licensees whose employees receive exposures of less than 5000 millirem in any quarter may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:
 - Supporting documentation that confirms that no employee will exceed 5000 millirem in any quarter; and
 - Proposed frequency of exchange
4. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages and secretarial personnel who work in the nuclear pharmacy but do not work with radioactive materials.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

E.2. MODEL PROGRAM FOR INTERNAL EXPOSURE

Conditions Under Which Bioassays Are Required

Personnel who prepare substantial doses of radioiodine may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Routine² bioassays are required when an individual handles in open form unsealed quantities of radioactive iodine that exceed the quantities shown in Table E.2. The quantities shown in Table E.2 apply to both the quantity handled at any one time or integrated as a total amount introduced into a process by an employee over any three-month period.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed ten percent (10%) of the limit in the year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay.

When quantities handled in unsealed form are greater than ten percent (10%) of the values in Table E.2, routine bioassays may be necessary under certain circumstances. **A written justification for not performing bioassays should be prepared and recorded for subsequent review during inspections whenever bioassays are not performed and the quantities handled exceed ten percent of the levels in Table E.2.**

All workers handling radioactive iodine or sufficiently close to the process so that intake is possible (e.g., within a few meters and in the same room as the worker handling the material) should participate in bioassay programs.

Frequency

A baseline measurement should be established for workers prior to beginning work with radioactive iodine in sufficient quantities that require bioassays.

A bioassay should also be performed within the last two weeks of the last possible exposure to radioactive iodine when operations are being discontinued or when the worker is terminating activities or potential exposure to these isotopes.

Follow-up bioassays should be performed within two (2) weeks of any measurements exceeding action point levels in order to confirm the initial results and, in the case of a single intake, to allow an estimate of the effective half-life of the radioiodine in the thyroid.

Timing

Biological samples or measurements should be obtained no sooner than one day (24 hours) and no later than four days (96 hours) following an exposure to conditions that require bioassays and every two (2) weeks or more thereafter as long as those conditions exist. When work with radioiodine is infrequent, bioassays should be performed within ten (10) days of the end of the work period during which radioactive iodine was handled.

² "Routine" in this instance means that an individual is assigned on a scheduled and repeatable basis to submit specimens for bioassay or to report for in vivo measurements. Either radiochemical bioassay of urine or in vivo counting is acceptable for estimating internal radioactivity burdens or intakes. In some cases, the licensee may wish to corroborate estimates from urinalysis data with in vivo determinations. Each facility should adopt procedures or obtain services best suited to its own needs.

Table E.2.

ACTIVITY LEVELS ABOVE WHICH BIOASSAYS FOR IODINE ARE NECESSARY		
	Activity Handled in Unsealed Form Making Bioassay Necessary	
	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1 mCi	10 mCi
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	10 mCi	100 mCi
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box or box leakage	100 mCi	1000 mCi

Notes: Quantities may be considered the cumulative amount in process handled by a worker during a three-month period: e.g., the total quantity introduced into a chemical or physical process over a three-month period, or on one or more occasions in that period, by opening stock reagent containers from which radioactive iodine may escape. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that radioiodine will remain in nonvolatile form and diluted to concentrations less than 0.1 mCi/mg of nonvolatile agent.

Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in nonfree form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped, crushed). However, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-handed column may then be applicable in those laboratories working only with Iodine-125 in radioimmunoassay (RIA) kits, the quantities of Iodine-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column.

Bioassay should be performed whenever an individual employee handles in open form (e.g., an open bottle or container) more than 50 mCi at any one time. Operations involving the routine use of Iodine-125 or Iodine-131 in an open room or bench should be discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1 mCi of Iodine-125 or Iodine-131 should be opened at least initially within hoods having adequate face velocities of 0.5 m/sec or more.

APPENDIX H

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

In addition to 641-41.2(21)

As a licensee, you must perform leak testing of sealed sources according to 641-40.32(2). The IDPH requires tests to determine whether or not there is any leakage from the radioactive source. The leak test should be performed at 6-month intervals unless otherwise authorized by your license.

The options for leak testing are:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.
2. Take the sample using a commercial leak-test kit and send the sample to the kit supplier who reports the results to you.
3. Perform the test and analysis yourself.

For Option 1, specify the name, address, and license number of the consultant or commercial organization.

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix H.1 or submit your own procedures.

For Option 3, describe the procedure for taking the test sample. Identify the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for these measurements. Include the minimum sensitivity for the instrument used for analysis and a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application.

You may use the following model procedure to leak-test sealed sources. If you follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix (H.1 and/or H.2) to IDPH Nuclear Pharmacy Regulatory Guide."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of 641-41.2(21). Say on your application, "We have developed a leak-test procedure for your review that is appended as Appendix H," and submit your leak-test procedure.

H.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES (IN ADDITION TO 41.2(21))

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
 - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
 - b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

- c. For the teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or crosshairs. Wipe the primary and secondary collimators and trimmers.
- d. If you are testing radium sources, you should also check for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak-test period.

H.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES (Option 3)

1. Select an instrument that is sufficiently sensitive to detect the levels in 40.32. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that is the same isotope and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of in accordance with IDPH rules.
7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain records for 5 years.

APPENDIX I

MODEL RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

In addition to 641-41.2 and 40.61

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to IDPH Nuclear Pharmacy Regulatory Guide."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of 641-41.2. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Appendix I," and submit your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

1. Protective clothing is to be worn at all times during the preparation, assay, and injection of radiopharmaceuticals. Wear long-sleeved laboratory coats, long pants, and closed toe and heel shoes in all areas where radioactive materials are being used. The protective clothing concept is for at least one protective layer over your skin in the event of a spill.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
5. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
6. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
7. Wear a finger exposure monitor during the elution of generators; during the preparation and assay of radiopharmaceuticals.
8. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
9. Never pipette by mouth.
10. Wipe-test by-product material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
12. With a radiation survey meter, survey daily for contamination the generator storage and kit preparation areas. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound,

and the date and time of receipt or preparation. A logbook should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each dosage in the dose calibrator.
15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
16. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should consider the use a cart or other device to move waste and other radioactive material.

APPENDIX J

MODEL SPILL PROCEDURES

In addition to 641-41.2 and 40.61(4)

You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the model spill procedure published in Appendix J to IDPH Nuclear Pharmacy Regulatory Guide."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as Appendix J" and submit your spill procedures.

MODEL PROCEDURES

MINOR SPILLS OF LIQUIDS AND SOLIDS

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the Radiation Safety Officer (RSO).
6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

MAJOR SPILLS OF LIQUIDS AND SOLIDS

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing. Flush contaminated skin with lukewarm water. Wash the effected area with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

MAJOR SPILLS AND MINOR SPILLS

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

Table J-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparison of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values), 51 CFR 1092.
2. "Gamma Radiation Levels for One Curie of Some Radionuclides," "Radiological Health Handbook", January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.
3. National Council on Radiation Protection and Measurements. "Safe handling of Radioactive Materials," NCRP Report No. 30, paragraph 2.3 and Table 2, 1964.
4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 CFR 29712, Table 1, June 3, 1981.

Table J-1 may need to be modified before being used for guidance in a specific area of use.

TABLE J-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major. Spills of the amounts shown below are considered minor.

<p>RELATIVE HAZARDS OF COMMON RADIONUCLIDES</p> <p>ESTIMATE THE AMOUNT OF RADIOACTIVITY SPILLED. INITIATE A MAJOR SPILL PROCEDURE BASED ON THE FOLLOWING DIVIDING LINE. SPILLS ABOVE THESE MILLICURIE AMOUNTS ARE CONSIDERED MAJOR, BELOW ARE CONSIDERED MINOR.</p>	
RADIONUCLIDE	MILLICURIES
Co-60, Sr-89, I-125, I-131	1
F-18, P-32, Co-58, Fe-59, Se-75, Sr-85, Y-90, In-111, I-123, Sm-153, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99m, Tl-201	100

APPENDIX K

MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

In addition to 641-40.65 and 641-41.2(11)"b"

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Pharmacy Regulatory Guide."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 641-40.65 and 641-41.2(11)"b". Say on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix K," and submit your procedure.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
 - a. For routinely used materials:
 - (1) Written records identifying
the authorized user or department,
isotope,
chemical form,
activity, and
supplier
 - (2) Verification that material received was ordered by an authorized user.
 - b. For occasionally used materials (e.g., therapeutic dosages):
 - (1) The authorized user who will perform the procedure will make a written request to confirm that the material received is what was ordered.
 - (2) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.

APPENDIX L

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

In addition to 641-40.65 and 39.5

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to IDPH Nuclear Pharmacy Regulatory Guide."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion 641-40.65 and 39.5. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix L," and submit your procedure.

MODEL PROCEDURE

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination according to 40.65.
2. The following procedure for opening each package will be followed:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
 - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is more than 10 millirems per hour at 3 feet (1 meter), stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface).
 - d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour on the external surface of the package.

Beta-gamma-emitting radionuclides; all radionuclides

with half-lives less than ten days.....22 dpm/cm²

All other alpha-emitting radionuclides.....2.2 dpm/cm²

- f. Open the package with the following precautionary steps:
 - (1) Remove packing slip.
 - (2) Open outer package following the supplier's instructions, if provided.
 - (3) Open inner package and verify that the contents agree with the packing slip.
 - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - (5) If anything is other than expected, stop and notify the RSO.
- g. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator

is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.

- h. Check the user request to ensure that the material received is the material that was ordered.
 - i. Monitor the packing material and the empty packages for contamination with a radiation survey meter before discarding.
 - (1) If contaminated, treat this material as radioactive waste.
 - (2) If not contaminated, remove or obliterate the radiation labels before discarding it.
 - j. Make a record of the receipt.
3. For packages received under the general license in 641-39.4(22)"i", the following procedure for opening each package will be followed.
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
 - b. Check to ensure that the material received is the material that was ordered.

APPENDIX M

MEASURING AND RECORDING MOLYBDENUM CONCENTRATION (641-41.2(34))

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Molybdenum-99 per millicurie of Technetium-99m at the time of administration.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Molybdenum-99 correction factor to convert the measured Molybdenum-99 to total Molybdenum-99.

The following model procedure may be used to measure the molybdenum concentration in Molybdenum-99/Technetium-99m generator elution. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M to IDPH Nuclear Pharmacy Regulatory Guide."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider the inclusion of all the features in the model procedure and carefully review the requirements of 641-41.2(34). Say on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as Appendix M" and submit your procedure for measuring and recording molybdenum concentration.

MODEL PROCEDURE

Each time a generator is eluted, record the items required by 41.2(34)"c." In addition, record:

1. Date the generator was received.
2. Product of the measured Molybdenum-99 activity and the correction factor noted by the manufacturer.

RECOMMENDED ACTION LEVEL: An 0.07 action level allows for the quicker decay of the Technetium-99m through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Molybdenum-99 to Technetium-99m would have doubled.

In conformance with 641-41.2(32)"d", the licensee must notify the IDPH if a leaking generator is detected.

APPENDIX N

MODEL PROCEDURE FOR AREA SURVEYS in addition to 641-40.27 and 41.2(26)

You may use the following procedure to perform area surveys. If you follow this procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to IDPH Nuclear Pharmacy Regulatory Guide."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 641-40.27 and 41.2(26). Say on your application, "We have developed survey procedures for your review that are appended as Appendix N" and submit your survey procedures.

MODEL PROCEDURE

AMBIENT DOSE RATE SURVEYS in addition to 41.2(26)

1. Surveys -- Restricted Areas:

- a. In areas such as *in vitro* labs where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
- b. In sealed source storage areas, survey quarterly with a radiation survey meter.
- c. Protective clothing should be surveyed by the wearer after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the restricted areas. Any contamination above expected levels should be reported to the RSO.

2. Surveys -- Unrestricted Areas:

Quarterly surveys should be accomplished in areas

- adjacent to restricted areas
- through which radioactive materials are transferred
- where radioactive material is temporarily stored before shipment

More frequent surveys will be necessary if radiation levels are suspect.

REMOVABLE CONTAMINATION SURVEYS in addition to 41.2(26)

1. Survey Areas:

In any area where the potential for spreading contamination is likely to occur, (cafeterias, snack bars, furniture and equipment), survey at least quarterly. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm² of removable contamination (200 dpm/100 cm² for isotopes of iodine). You

must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm to disintegrations per minute or dpm).

3. Immediately notify the RSO if you find levels, which exceed the established action levels. See Table N-1 below for guidance in establishing your action levels.

RECORDS

1. Records must include the information in 41.2(26)"h" and 40.82 as well as actions taken in the case of excessive dose rates or contamination and follow-up survey information.
2. The RSO will review and initial the record at least monthly and promptly in those cases in which action levels were exceeded.

<p style="text-align: center;"><u>TABLE N-1</u></p> <p style="text-align: center;">RECOMMENDED ACTION LEVELS IN DPM/100 CM² FOR SURFACE CONTAMINATION</p>		
	<p>P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198</p>	<p>Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, TI-201</p>
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

3. Maintain records for three (3) years.

APPENDIX O

MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS

In addition to 641-40.15, 16, 17, and 18; 41.2(29) and 41.2(35)

ADEQUACY OF FACILITY FOR HANDLING XENON-133

You must have adequate equipment and operating controls to ensure that radioactivity in air is maintained within regulatory limits. Describe the scope and extent of your operations involving Xenon-133. Include the form in which Xenon-133 will be received (e.g., ampoules containing 1 curie or more, unit-dose vials), the form in which Xenon-133 will be dispensed, and the manipulations involved between receipt and dispensing. This description should include an estimate of the fraction of Xenon-133 lost during storage and manipulation.

It is assumed that you will receive Xenon-133 in unit-dose vials and redistribute the product to your customers upon request. One manufacturer estimated a loss factor of 0.5% per day from its unit-dose vials. This value has been used by some applicants and the IDPH staff has found this acceptable. If you will use a more complicated process than simply redistributing unit-dose vials, you should provide information about your methods for estimating the loss factor.

O.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES IN WORK AREAS.

For restricted areas 641-40.15(4) limits derived air concentrations (DAC) for Xenon-133 in air to 1×10^{-4} $\mu\text{Ci/ml}$. In order to demonstrate compliance with this regulation, you may state that Xenon-133 will be stored in a fume hood with adequate airflow and that all work involving Xenon-133 will be conducted in that fume hood. If you do not so state, you should submit calculations to demonstrate compliance.

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, OSD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the derived air concentration (DAC) for Xenon-133 (or other gas to be used) to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of five (5) rems (50 mSv) and divide this number by five (5) rems.
 - a. This yields the fraction of the dose limit of five (5) rems that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in Appendix B to Chapter 40 in Table 1, column 3.
 - b. If the highest annual external dose is 2 rems, and the listed DAC value for xenon-133 is $1\text{E-}4$ mCi/ml, then the modified DAC value should be based on 3 rems that could still be incurred from internal exposure.
3. The following calculations must be made:
 - a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
 - b. The estimated activity released to the restricted areas.
 - (1) The total activity released to the restricted area divided by the total air exhausted must be less than the applicable DAC for a restricted area. The total activity released to the

restricted area is activity used each week multiplied by estimated fractional loss per study. The total air exhausted is the sum of all exhaust rates multiplied by the length of the workweek.

- (2) If this is not the case, plan for fewer studies and do the calculations again. An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.

O.2 PUBLIC DOSE FROM AIRBORNE EFFLUENT

If you are not directly venting gases to the atmosphere, you may respond by saying, "We will not directly vent gases to the atmosphere and, therefore, no effluent estimation is necessary."

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value of Table II of Appendix B to Chapter 641-40. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week. The quotient must be less than the applicable DAC value for an unrestricted area.

If you will follow the model procedure below for calculating release concentrations, you may respond by saying "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix O.2 to IDPH Nuclear Pharmacy Regulatory Guide."

If neither of the above applies, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 641-40.15, 16, 17, and 18, 41.2(29) and 41.2(35). Say on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as Appendix O.2" and append your procedure for monitoring airborne effluent concentration.

641-40.27(2) limits Xenon-133 concentration at the boundary of the unrestricted area to 5×10^{-7} $\mu\text{Ci/ml}$ when averaged over one year. The calculations to estimate the concentration of Xenon-133 in effluents to unrestricted areas and to show compliance with 641-40.27(2)"b"(1) may be performed as follows:

1. Estimate the maximum amount of Xenon-133 to be released per week, value "A." Your estimate should be based on your total possession limit multiplied by your estimated loss factor.
2. Determine the airflow rate of the exhaust system and describe the methods used for measuring the airflow rates. **The airflow rate should be determined by actual measurement.** Linear airflow (i.e., feet per minute) must be multiplied by the area of the fume hood opening (in square feet) to obtain the airflow rating in cubic feet per minute.
3. Calculate the airflow per week, value "V."
4. Calculate the average concentration for unrestricted areas. 641-40.27 requires that

$$C = A/V \leq 5 \times 10^{-7} \mu\text{Ci/ml}$$

The following gives the amount of Xenon-133 that can be released per week without exceeding an average concentration of 5×10^{-7} $\mu\text{Ci/ml}$:

EXHAUST RATE (FT ³ /MIN)	AVERAGE RELEASE OF XENON-133 PER WEEK (MCI)
100	14.3
500	71.4
1,000	142.7
1,500	214.1

Some Useful Conversions

1 mCi	=	10 ³ μ Ci
1 ft ³	=	2.832 x 10 ⁴ ml
1 ft ³ /min	=	1.699 x 10 ⁶ ml/hr

Airflow ratings should be measured periodically to ensure continued compliance. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application.

O.3 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, calculations should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

1. Collect the following data:
 - a. A, the highest activity of gas in a single container, in microcuries;
 - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser values), in milliliters per minute;
 - c. Q -- the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system.
 - d. C -- the modified derived air concentrations (DAC) in restricted areas.
 - e. V -- the volume of the room in milliliters.
2. For each room make the following calculations:
 - a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
 - b. The evacuation time $t = -V/Q \times \ln (C \times V/A)$.
3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted

- 2.0 mrem in any 1 hour from external sources, and
- 100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.

Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

O.4 RECORDS

1. Measure ventilation rates in areas of use at intervals not to exceed 6 months.
2. Maintain these records for 3 years.

APPENDIX P

REQUESTS FOR AUTHORIZATION TO REDISTRIBUTE VARIOUS ITEMS

Some nuclear pharmacies have requested authorization to conduct activities that may be characterized as "redistribution" of various items can be authorized on the nuclear pharmacy license. "Redistribution" usually involves obtaining an item (e.g., a reagent kit) from an approved supplier and selling it to the nuclear pharmacy's customers with little or no change in the original packaging, shielding, etc.

Note: If you wish to **manufacture and distribute** reagent kits, sealed calibration or reference sources, or in-vitro kits, you should contact IDPH for further licensing information.

A. -- REDISTRIBUTION OF REAGENT KITS

If you want to redistribute reagent kits to group medical licensees, you should:

1. Specify that reagent kits to be redistributed will have been obtained from a manufacturer authorized to distribute reagent kits in accordance with a specific approval issued pursuant to 641-39.4(29)"K".
2. Specify that reagent kits will be redistributed as received from the manufacturer in the "kit sleeve" (i.e., cardboard enclosure holding a Styrofoam container with multiple reaction units). Verify that the manufacturer-supplied package insert, leaflet, brochure, or other document that describes the procedures to be followed and the equipment and shielding to be used in processing radioactive material with the reagent kit also will be enclosed.

B. -- REDISTRIBUTION OF GENERATORS

If you want to distribute generators to medical licensees, you should:

1. Specify that all generators to be redistributed will have been obtained from a manufacturer authorized to distribute the generators in accordance with a specific license issued pursuant to 641-39.4(29)"K".
2. If unused generators will be redistributed, specify that the unused generators will be redistributed without opening or altering the manufacturer's packaging.
3. If used generators will be redistributed:
 - (a) Specify that, during the time the generator is being used by the nuclear pharmacy, the generator will be used only in accordance with the manufacturer's instructions.
 - (b) Specify that, at the end of the nuclear pharmacy's use of the generator, the generator will be repackaged in its original shipping container in accordance with IDPH and DOT regulations. Commit to completing wipe tests, measurements of radiation levels (surface of and 1 meter from the package) and shipping papers. Verify that security seal and appropriate DOT labels will be affixed.
 - (c) Submit actual color samples of labels you will affix to the generator shield. (Note that labels must fulfill the color, symbol, and wording requirements of 641-40.60(136C) in addition to 641-39.4(29)"K"(4) and (5).
 - (d) Specify that you will ensure that each redistributed generator is accompanied by the manufacturer supplied package insert, leaflet, or brochure that describes the

procedures to be followed and the equipment and shielding to be used when using the generator.

- (e) Specify that you will not redistribute generators beyond the expiration date shown on the generator label.
- (f) Submit correspondence to and from FDA that describes your proposed redistribution of used generators and indicates FDA's approval and any necessary conditions that FDA believes must be fulfilled. Submit evidence that you have fulfilled the conditions specified by FDA.

C. -- REDISTRIBUTION OF SEALED SOURCES-CALIBRATION AND REFERENCE SOURCES

If you want to redistribute sealed calibration or reference sources to group medical licensees, you should:

1. Specify to what categories of licensees (e.g., group medical licensees, other licensees specifically authorized to receive the sources) you wish to redistribute the sources.

NOTE: Although a nuclear pharmacy's customers for the sources are primarily group medical licensees, many nuclear pharmacies also request authorization to redistribute the calibration or reference sources to other specific licensees.

2. Specify that the calibration or reference sources to be redistributed will have been obtained from a manufacturer authorized to distribute the sources in accordance with a specific license issued pursuant to 641-39.4(29)"r".
3. Specify that the manufacturer's labeling and packaging will not be altered.
4. Specify that redistributed sources will be accompanied by the manufacturer supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

D. -- REDISTRIBUTION OF *IN VITRO* KITS

Many nuclear pharmacies have requested authorization to redistribute *in vitro* kits to general licensees and to specific licensees. Guidance on obtaining these authorizations is given below.

If you want to redistribute *in vitro* kits to general licensees, specify that:

1. The prepackaged *in vitro* kits to be redistributed will have been obtained from a manufacturer authorized to distribute the *in vitro* kits in accordance with a specific license issued pursuant to 641-39.4(29)"h".
2. The manufacturer's packaging and labeling of the *in vitro* kits will not be altered in any way.
3. Each redistributed *in vitro* kit will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

If you want to redistribute *in vitro* kits to specific licensees, specify that:

1. You will obtain prepackaged *in vitro* kits as described in 641-39.4(22)"l" for redistribution to specific licensees.

2. You will ensure that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed *in vitro* kits do NOT reference general licenses, exempt quantities, or regulations that authorize a general license.
3. You will ensure that labeling on redistributed *in vitro* kits conforms to the requirements of 641-40.60(136C).

APPENDIX R

MODEL PROCEDURE FOR WASTE DISPOSAL

In addition to 641-40.70, 40.88 and 41.2(30))

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that was published in Appendix R to IDPH Nuclear Pharmacy Regulatory Guide."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of 641-40.70 and 41.2(30). Say on your application, "We have developed a procedure for waste disposal for your review that is appended as Appendix R" and attach your procedure.

OVERVIEW

There are four commonly used methods of waste disposal:

- release to the environment through the sanitary sewer or by evaporative release;
- decay-in-storage (DIS);
- transfer to a burial site or back to the manufacturer; and
- release to in-house waste.

With the exception of the patient excreta (see 641-40.72) and generally licensed *in-vitro* kit exemptions (see 641-39.4(22)"i"), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See 641-38.4(1) and 40.88.)

GENERAL GUIDANCE

1. All radioactivity labels must be defaced or removed from containers and packages before disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that unnecessary radioactive waste is not created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 641-40.72. There are specific limits based on the total sanitary sewerage release of your facility. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.
2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to Chapter 641-40. These limits normally apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.
3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (641-40.74). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by decay-in-storage. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container and unused dosages in another). Smaller facilities may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date that it was sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the decay-in-storage area.
3. Decay the material for at least 10 half-lives.
4. Before disposal as in-house waste, monitor each container as follows:
 - a. Check your radiation detection survey meter for proper operation.
 - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
 - c. Remove any shielding from around the container.
 - d. Monitor all surfaces of each individual container.
 - e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be sure that no radiation labels are visible.
 - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, and then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mr/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 641-39.5 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Measure the dose rate and removable contamination levels required by 39.5(15).
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from *in vitro* kits that are generally licensed pursuant to 641-39.4(22)"i" is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL RADIATION SAFETY PROGRAM AUDIT CHECKLIST

ANNUAL AUDIT CHECKLIST

ORGANIZATIONAL STRUCTURE

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| a. Radiation Safety Officer (RSO) same as listed on the license | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Visiting Authorized Nuclear Pharmacist(s) | | | |
| (1) Has written permission. [41.2(12)"a"(1)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Visitor authorized pharmacist's license on file. [41.2(12)"a"(2)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (3) Uses materials under licensee's license or 60 days per year or less. [41.2(12)"a"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (4) Records maintained five (5) years after the visiting authorized user's last visit. [41.2(12)"c"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

AUDIT HISTORY

- | | | | |
|-----------------------------------|------------------------------|------------------------------|-----------------------------|
| a. Last audit conducted on: _____ | | | |
| b. Deficiencies identified. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Were they corrected? | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

SCOPE OF PROGRAM

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| Have there been radiation safety program changes? [41.2(4)"f"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| If yes, list changes | | | |

TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Instructions to workers provided. [40.111] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Training program conducted according to license commitments. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

FACILITIES, MATERIALS, AND EQUIPMENT

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Facilities are as described in the license application. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Storage and use of radioactive material | | | |
| (1) Adequate method to prevent unauthorized individuals from entering restricted area. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Radioactive material secured to prevent unauthorized removal or access. [40.55"a"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Dose Calibrator | | | |
| (1) Constancy checked. [41.2(17)"b"(1)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Linearity tested. [41.2(17)"b"(3)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (3) Accuracy tested. [41.2(17)"b"(2)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (4) Geometry dependence test. [41.2(17)"b"(4)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (5) Readings mathematically corrected if linearity error is greater than 10%. [41.2(17)"c"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (6) Records maintained. [41.2(17)"e"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (7) RSO signs linearity, accuracy, and geometry dependence tests. [41.2(17)"e"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| d. Survey instruments. | | | |
| (1) Appropriate operable survey instruments. [41.2(32); 41.2(36); and 41.2(40); 41.2(42)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Calibration, as required. [41.2(18)"a"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (3) Records maintained. [41.2(18)"e"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Syringes properly labeled. [41.2(23)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Vials containing RAM properly shielded. [41.2(24)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Vials properly labeled. [41.2(25)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

RADIOLOGICAL PROTECTION PROCEDURES

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| a. Individual has understanding of procedures. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (1) In general, rules for safe use of RAM. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) In emergency procedures | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

MATERIALS

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Molybdenum-99 breakthrough tests performed. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Records Molybdenum-99 breakthrough tests maintained. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Leak tests of sealed sources performed at appropriate intervals. [41.2(21)"b"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (1) Leak test records in units of microcuries. [41.2(21)"d"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Leak test records signed by RSO. [41.2(21)"d"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (3) Records of leak tests kept for five (5) years. [41.2(21)"d"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Inventories | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (1) Quarterly inventory of sealed sources. [41.2(21)"g"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Inventory records signed by RSO. [41.2(21)"g"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (3) Records of leak tests and inventories kept for five years. [41.2(21)"g"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Procedure for opening packages adequate. [40.65(5)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Incoming packages monitored for radioactive contamination. [40.65(2)"a" or "c" and 40.65(3)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Incoming packages monitored for external radiation levels. [40.65(2)"b" and 40.65(3)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Transfers performed, as required. [39.4(41)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Records of receipt surveys. [40.82(1)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Records of receipt, transfer, & disposal of radioactive material. [38.4(1)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

AREA SURVEYS

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Ambient dose rate surveys performed. [41.2(26)"a" and "b"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Contamination surveys conducted. [41.2(26)"e"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Trigger levels established. [41.2(26)"d" and "g"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Dose rate survey records in mR/hr. [41.2(26)"h"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Contamination survey records maintained in dpm/100 cm ² . [41.2(26)"h"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

PERSONNEL RADIATION MONITORING – EXTERNAL

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Supplier NVLAP approved. [40.36(3)"a" and "b"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Dose(s) exceeded regulatory limits. [40.15] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. ALARA program implemented. [41.2(7)"a"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Written description of ALARA program available. [41.2(7)"d"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

PERSONNEL RADIATION MONITORING – INTERNAL

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Bioassay program implemented and performed at proper intervals | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Radioactive gases | | | |
| (1) Clearance time and safety procedures are posted. [41.2(35)"e"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Ventilation rates checked for negative pressure at six-month intervals. [41.2(35)"f"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

WASTE DISPOSAL

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Radioactive material disposed of as authorized. [40.70(1)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Record of disposal by decay in storage maintained. [41.2(30)"b"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Survey of waste before disposal. [40.36] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Records of waste surveys. [40.82(2)"d"] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

NOTIFICATION AND REPORTS

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| a. Notifications and reports provided to individuals. [40.112] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Reporting theft or loss compliant with rules. [40.95] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Compliant regarding overexposures notification of incidents. [40.96] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Compliant regarding reporting of excessive levels and concentrations. [40.97] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Termination reports furnished, if requested by workers. [40.112(5)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

POSTING AND LABELING

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Radiation Areas posted. [40.61(1)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. High Radiation Areas posted. [40.61(2)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Use or storage areas posted "Caution Radioactive Material." [40.61(5)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Containers or devices labeled. [40.63] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Notice to Workers posted. [40.110(1) and (2)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Notice to Employees posted. [40.110(3)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

TRANSPORTATION (641-39.5) AND 49 CFR 171-178

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| a. Authorized packages used. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. DOT-7A performance test records on file. [173.415(a)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. For special form sources, performance test records on file. [173.476(a)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Packages properly labeled. [172.403(b)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Packages properly marked. [172.301(a)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Proper shipping papers prepared. [172.200] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Shipping paper contains emergency response telephone number. [172.201(d)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

SUMMARY OF REVISIONS

<u>REVISION</u>	<u>SECTION</u>	<u>DESCRIPTION</u>
01/08/99	Item 11.2	Auditing guidance
	Appendix E	Modified exchange frequency criteria Modified bioassay program to reflect current rule revision
	Supplement A	Model Audit Checklist
10/06/00	Item 11.2	Delete references to Portable Gauges
12/27/00	ALL	Reformat text. Changed address for Bureau of Radiological Health.
01/18/02	Section 7	Added information concerning inspections.
06/19/02	Appendix J	Added additional isotopes to spill procedure.
06/20/02	Appendix E	Corrected action level for monthly exchange of extremity dosimeters from 500 mrem per quarter to 5000 mrem in any quarter. Replaced discussion on bioassays in Section E.2
03/13/03	Section 1.2	Replace the website address of the IDPH rules and publications.
12/07/04	Appendix I	Added requirement for long-sleeve laboratory coats.
07/01/05	ALL	Changed address for the Bureau of Radiological Health
07/17/07	Appendix B	Added new Model Delegation of Authority
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.
08/08/12	Item 4	Updated rule references for authorized users.